DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 21, 2006

W/L 04-07

Elizabeth Terris
President
Sam's Homemade Cheesecake Inc.
7666 Miramar Road
San Diego, CA 92126

Dear Ms. Terris:

An inspection of your human food manufacturing facility located at 7666 Miramar Road, San Diego, CA, conducted August 10 through 14, 2006, found significant deviations from the Current Good Manufacturing Practice (cGMP) regulations for food manufacturers (Title 21, Code of Federal Regulations, Part 110). At the conclusion of the inspection you were issued a Form FDA-483, Inspectional Observations, (copy attached) which listed a number of gross insanitary conditions present at the time of that inspection. These conditions cause the foods being manufactured at your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth, or whereby they may have been rendered injurious to health.

Our inspection found the following serious deviations from the cGMP regulations:

1. Your employees did not wash and sanitize their hands prior to handling product. [21 CFR 110.10(b)(3)] Specifically, employees failed to wash hands after touching unsanitary surfaces and prior to touching finished cheesecakes.

2. You failed to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food-contact surfaces. [21 CFR 110.35(a)] Specifically, an employee was observed placing a knife on the floor in order to spray it with water. The knife was subsequently dipped in sanitizer and

returned to use. In addition, an employee was observed wiping out the frosting mixer with a rag that had been soaking in a bucket of cloudy water. No detergent or sanitizer was used to clean the mixer.

3. Failure to use and store toxic materials in a manner that protects against contamination of food. [21 CFR 110.35(b)] Specifically, a bottle of Advil was observed sitting on a pallet in the cake finishing room.

4. Failure to provide plumbing of adequate size and design and adequately installed to avoid constituting a source of contamination to water supplies or creating an unsanitary condition. [21 CFR 110.37(b)(3) and (b)(5)] Specifically, there is no backflow prevention on the water outlet (hose bib) used for cleaning in the ware washing room. A hose connected to the hose bib was observed with the spray nozzle end sitting in the bottom of one of the compartments of the ware washing sink.

5. Your plant is not constructed in such a manner as to prevent drip and condensate from contaminating food. [21 CFR 110.20(b)(4)] Specifically, racks of ready-to-eat cheesecakes and other desserts were observed uncovered and sitting below leaking condensing units in the freezer. Frozen condensation was observed on the top of one of the racks of product.

These violations are not intended to be an all-inclusive list of deficiencies at your manufacturing facility. As a producer of human foods, you are responsible for assuring that your establishment is in compliance with all requirements of the federal regulations. Additionally you should be vigilant in continually meeting these requirements.

Several of the violations noted during this inspection are similar to those cited during previous inspections conducted by both FDA and the State of California Food and Drug Branch. In response to our April 2004 inspection you provided a written response committing to corrective action. We did not find the committed corrective actions comprehensively and continuously implemented. We are very concerned about this situation.

You should take prompt action to correct and prevent recurrence of all deviations. Failure to promptly correct these deviations may result in regulatory action including, but not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific actions taken to bring your firm into compliance with the law. Your response should be specific and comprehensive, including an explanation of each step being taken to correct the cGMP violations and prevent their recurrence. Please include copies of any available documentation showing that corrections have been made. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. If you have any

questions regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer at (949) 608-4439.

Please direct your written response to the attention of:

Pamela B. Schweikert
Director, Compliance Branch
United States Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

Sincerely,

Alonza Cruse
District Director

Cc: Department of Health Services
Attn: Chief, Food and Drug Branch
P.O. Box 997413, MS-7602
Sacramento, CA 95899-7413